IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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WALTER SHUKER, et al.	:	CIVIL ACTION
	:	NO. 13-CV-6158
Plaintiffs	:	
	:	
vs.	:	Philadelphia, Pennsylvania
	:	July 16, 2014
SMITH & NEPHEW, PLC, et al.	:	
Defendants	:	ORAL ARGUMENTS HEARING

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BEFORE THE HONORABLE JUAN R. SANCHEZ
UNITED STATES DISTRICT JUDGE

- - -

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(At 1:33 p.m. in Courtroom 11a.)

ESR OPERATOR: Court is now in session. The Honorable Juan R. Sanchez presiding.

THE COURT: Good afternoon, everyone.

ALL PRESENT: Good afternoon, your Honor.

THE COURT: You may be seated.

This is the matter of Walter Schuker versus -- defendants -- Smith & Nephew. PLC and Smith & Nephew, Inc.

I believe I have Mr. Zajac.

MR. ZAJAC: Yes, your Honor, good morning --

THE COURT: And --

MR. ZAJAC: -- good afternoon.

THE COURT: -- Mr. Astrachan.

MR. ASTRACHAN: Good afternoon.

THE COURT: I believe we also have attorney Petrowski.

MS. PETROWSKI: Good afternoon, your Honor.

THE COURT: And we have Attorney O'Quinn.

MR. O'QUINN: Good afternoon, your Honor.

THE COURT: And I believe, lastly, we have Attorney Mahady.

MR. MAHADY: Good afternoon, your Honor.

THE COURT: All right.

Perhaps, what I would like to do first -- I'm going to reverse the order a little bit. And I want to hear argument on the motion pertaining to Smith & Nephew, PLC, the personal-

jurisdiction issue.

MS. PETROWSKI: Sure.

THE COURT: All rise. Why don't you come forward.

Now, since you filed your motion to dismiss as you well know, the plaintiff have filed their second amended complaint.

And my question to you is, do the allegations of the proposed second amended complaint impact your jurisdictional argument and if so, how?

MS. PETROWSKI: To be honest, your Honor, because our motion was directed to the first amendment complaint, I don't know the answer to that question.

THE COURT: Okay. So, let's -- let's then move on.

PLC involvement with the Birmingham Hip Resurfaces System and in particular, the R3 medal liner, what is PLC's involvement with those systems?

MS. PETROWSKI: Sure.

A couple of things, your Honor.

First, with respect to the sworn statements that we've attached to our motion --

THE COURT: Right.

MS. PETROWSKI: -- those relate to the R3 Acetabular system.

THE COURT: Right.

MS. PETROWSKI: And the reason for that, your Honor,

is because all of the allegations in the first amended complaint go back to the acetabular system, themselves. So, we did not address the issue with respect to the BHR.

That being said, your Honor, PLC is a holding company and the sworn statements of the affidavits would apply with equal force. PLC is not in the business -- as plaintiffs contend -- of designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing and selling medical devices -- any medical devices, including the acetabular system.

THE COURT: Okay.

But they -- they have put forward some evidence with regards to PLC and -- that that claim meets the -- the criteria for personal -- personal jurisdiction, either on a specific jurisdiction theory or -- or general jurisdiction, but particularly, personal jurisdiction regarding what page of -- of the holding company and what it advertises and things that they have done.

So, what is your response to that?

MS. PETROWSKI: Sure, your Honor.

I -- I don't think that any of the conclusory statements made in the plaintiffs' response refute the specific sworn statements in either of our affidavits. That -- that being said, let's look at some of the specific things that -- why I say that -- and apply it also in the context of the law.

With respect to specific jurisdiction, an assertion of specific jurisdiction is only proper where plaintiffs' claims arise out of conduct that defendant purposefully directs at Pennsylvania. And this comes out of the O'Connor versus Sandy Lane Hotel case that's cited in our case -- or in our -- in our brief.

Yet none of the so-called jurisdictional facts that the plaintiffs cite demonstrate that their claims -- which stem from the manufacturer, the advertising, the sale and implementation of system -- arise out of conduct that PLC purposely -- purposefully -- directed at Pennsylvania.

So, first, let's look at the arguments and I can tick through them, one after another, your Honor.

Plaintiff's first claim that PLC purposefully directed conduct towards Pennsylvania by -- again -- directly designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing and/or selling medical devices, including the R3 Acetabular system and/or parts from the BHR System.

But -- but, again, your Honor, this is a conclusory statement that is directly and wholly contradicted by the sworn affidavits of Susan Swabey and John Clausen, one representative from PLC and one representative From INC.

In addition to that very broad and conclusory statement, plaintiffs contend that PLC has actively traded on

the floor of the New York Stock Exchange. In fact, your Honor, PLC's stock is not traded on the New York Stock Exchange. What is traded is something known as an American Depository Share and that's a security that's held or issued by a U.S. Depository Bank outside of the U.S., that represents one or more shares of foreign stock.

And, your Honor, courts have held that listing ADSs, these American Depository Shares does not in and of itself without more and this goes back to the test of whether the claims arise out of conduct that was purposefully directed at Pennsylvania.

So, the listing of these ADSs on the New York Stock Exchange does not in and of itself confer jurisdiction. Again, your Honor, the inquiry has to be whether plaintiffs' claim arise out of conduct that PLC purposefully directed towards Pennsylvania.

And here there's no argument by plaintiffs nor can there be, that their product's liability and breach of warranty claims somehow arise out of these ADSs being listed on the New York Stock Exchange.

Third, plaintiffs contend that PLC spent millions of dollars on research and development in 2013. And what they say, your Honor -- if you look at their brief -- they say that:

Presumably, at the time of the development of the R3 Acetabular System, PLC spent millions to develop

products for distribution into Pennsylvania.

There's nothing to substantiate these, your Honor. If -- if you look at where they found this particular excerpt, it came from the Smith & Nephew website. And the excerpt, itself -- as plaintiffs indicate on the face of their brief -- comes from 2003. There is nothing -- or I'm sorry -- from 2013. There is nothing tying this excerpt from 2013 to the relevant time period of when the system, either, the R3 Acetabular System or the BHR System was actually developed.

The website, furthermore, it doesn't indicate that it was PLC as opposed to another Smith & Nephew entity that spent the money on research and development. Moreover, it -- it doesn't say anything to suggest that the money -- these millions of dollars -- were actually spent on the system at all, it's just a general reference to research and development.

And remember, your Honor, the burden of proof is on plaintiffs here. They have to show by a preponderance of evidence, that jurisdiction attaches to PLC.

And here, if you -- if you really drill down and look at this excerpt, especially, this particular argument, it's nothing but speculation, particularly, in light of the sworn statements to the contrary that PLC is not involved in the development of medical devices, including the R3 Acetabular System.

Fourth, plaintiffs contend that the president of INC.,

is also an executive officer of PLC. However, again, if you look at the sworn statements, the boards are not overlapping, your Honor, there may be one director that is an executive -- the president might be an executive officer of PLC. But there's no direct alignment among the officers of INC and the officer of PLC. And plaintiffs make no claims to the contrary, moreover, the affidavits, themselves, bear out that they do have separate officers and directors.

And the case law is pretty clear on that front as well, your Honor, that there -- there may be an officer that overlaps, but it's only in situations where the boards are completely congruent, that jurisdiction, typically, attaches. And, again that's just not the case here.

Fifth, plaintiffs contend that there are press releases announcing -- announcing -- both the launch and the recall of the system on the website for PLC. Again, this is Smith & Nephew's website and these press releases are in Exhibits F and I of plaintiffs' response brief.

And -- and again, if you look at those press releases, themselves -- and perhaps, we should do that right now.

(Pause at 1:44 p.m.)

THE COURT: I have them.

MS. PETROWSKI: So, if you'd turn, your Honor, to Exhibit F of plaintiffs' response brief. This is an excerpt from the website that's titled, Smith & Nephew Launches the R3

Acetabular System.

THE COURT: Hm-hmm.

MS. PETROWSKI: And again, plaintiffs are claiming here that PLC is -- is making this release. But if you look at the text of the release, itself, it says:

> Memphis, Tennessee and San Francisco, California, March 6th, 2008, Smith & Nephew, Inc. orthopedic reconstruction business today announced the global launch of the R3 Acetabular System.

This doesn't say anything in here that PLC was announcing that system.

Similarly, with respect to the recall of the system and also, the launch of the system, plaintiffs contend that inquiries at the bottom of these press releases are supposed to be directed to PLC. And, yes, that is true, your Honor, there is a provision in these press releases for inquiries to be directed to an individual at PLC.

It's also equally true that if you look at these press releases, there is also a provision for media inquiries, investor inquiries to be directed at someone at INC., as well. And there are contacts both for someone at PLC and someone at INC.

The plaintiffs contend that PLC tries to distance itself from the BHR in -- in our motion. I -- I don't think that that was an intentional act on our part, your Honor, as I

stated at the outset, the reason why our motion speaks to the R3 Acetabular System is because all of the allegations of the first amended complaint relate back to that system, not the BHR.

But in any event, your Honor, as I stated at the outset, as the sworn statements of John Clausen and Susan Swabey clearly demonstrate, PLC is a holding company, it's simply not involved in the manufacture, sales, distribution, et cetera of medical devices.

And there's nothing in any of the statements, arguments, so-called evidence that plaintiffs put up, to review -- to refute or somehow counter the statements that are in the affidavits.

THE COURT: Very well.

MS. PETROWSKI: At --

THE COURT: Go ahead.

MS. PETROWSKI: -- do you have a question?

THE COURT: I -- I -- why don't you finish.

MS. PETROWSKI: Okay.

THE COURT: I do have a question, because while I may agree with you, that on the record, I think you have compelling case for a dismissal of the case on the grounds of no personal jurisdiction. The Third Circuit has instructed our Courts, that we should allow jurisdictional discovery unless we believe that jurisdictional discovery is frivolous.

So, are their claims here frivolous, so that allowing

jurisdictional would be futile?

MS. PETROWSKI: I think that I would address that slightly differently, your Honor. And -- and I guess, I would say, first of all, I do think that they're frivolous as they pertain to PLC, because I don't think that PLC is in the business of manufacturing, distributing, marketing, et cetera. Any -- any of the things that plaintiffs claim that PLC has been doing to justify jurisdiction, we simply don't.

But I'd also like to take it a step further, your Honor, jurisdictional discovery should not be authorized where -- as here -- plaintiffs failed to make a preliminary showing of jurisdiction. And this gets back to the fact that under the law, your Honor, the burden is on plaintiffs to show by a preponderance of the evidence that jurisdiction attaches.

And in order to do so, your Honor, the Third Circuit has said that plaintiffs must -- quote:

> Present factual allegations that suggests with reasonable particularity, the possible existence of the requisite contacts between the party -- here, PLC -- and the forum state -- Pennsylvania.
>
> And indeed, the Third Circuit has cautioned that:
>
> A plaintiff may not undertake a fishing expedition based only upon bare allegations under the guise of jurisdictional discovery.
>
> And here, I would argue, your Honor, that plaintiffs

have not alleged any facts that suggest with reasonable particularity, that PLC maintains minimum contacts with Pennsylvania required to support an exercise of personal jurisdiction.

Plaintiffs have not alleged nor can they demonstrate:

One, that their claims arise out of any PLC contact -- conduct.

Or, two, that PLC purposefully directed any such conduct to PLC.

And if you look at what the plaintiffs are seeking in their discovery, I don't know how it can be characterized as anything other than a fishing expedition. Plaintiffs' purported discovery requests on jurisdictional issues, your -- alone, your Honor -- include fifteen requests to admit and over sixty Interrogatories with multiple sub parts.

And if you look -- if you drill down in to the discovery requests -- and what exactly it is that plaintiffs are seeking, I -- I'd contend that they're seeking the very facts that they should have alleged in the first instance to show with reasonably particularity, the possible existence of the requisite contacts between PLC and Pennsylvania.

So, for example, your Honor, if you look at Interrogatory Nos. 11, 12, 15, 17 through 21, 23 through 25 and 27 through 36 and by my tally, that's twenty-one of the sixty that they've propounded. These Interrogatories seek detailed

information regarding and any and all contacts during the past ten years between PLC, its affiliates or its subsidiaries and any person or entity in Pennsylvania, including customers, affiliates and subsidiaries.

Now, I would contend, your Honor, you -- I would contend, your Honor, that this is the very stuff that should form the basis of their allegations with respect to jurisdiction.

And then, your Honor, almost all of the remaining discovery requests cover subjects that have already been answered by the sworn statements that were attached to our motion and some of these issues pertain to the alter-ego theory of jurisdiction.

So, in particular, whether PLC and INC observed corporate formalities? Whether PLC controls the day-to-day operations of INC? Whether PLC conducts any business related to medical devices and including the R3 Acetabular System? Whether PLC approves or directs any business decisions relating to the system?

And, again, your Honor, if you look at -- there's one Eastern District of Pennsylvania case -- this is the FC Food Company versus Holt Cargo System case that we've cited to in our brief. There they denied jurisdictional discovery where plaintiffs countered defendant's sworn affidavits with mere speculation. And I would contend that that's exactly what's

going on here as we have discussed previously.

And, finally, your Honor, if you'd like to hear there is plaintiffs' argument with respect to the alter-ego theory.

THE COURT: Go ahead, briefly --

MS. PETROWSKI: Okay.

THE COURT: -- you could respond to that.

MS. PETROWSKI: Sure.

And, again, I'd like to discuss -- sort of -- the legal standard that applies to this argument.

The Third Circuit has held that the requirements for piercing the corporate veil are quote, demanding, unquote.

And the case law within the Third Circuit highlights many factors, courts may consider in assessing whether a parent is the alter ego of its subsidiary. But, ultimately, the plaintiff must demonstrate that, quote:

> The degree of control exercised by the parent is greater than normally associated with common ownership and directorship.

And for that, your Honor, we rely on Arch v. The American Tobacco Company case.

And so, plaintiffs make a number of arguments, that PLC owns indirectly INC, that PLC owns the rights to the trademark of Smith & Nephew in the United States, that PLC and INC share common websites.

They, again, go through the press releases, both

launching the system and subsequently, recalling the system. And they contend that this is the -- the stuff to show that -- the degree of control exercised by PLC is greater than that normally associated with common ownership and directorship.

But -- but, again, your Honor, none of these facts that plaintiffs put forth contradict the affidavits that have been submitted by Susan Swabey and John Clausen. PLC is a holding company, again, it -- it doesn't conduct operations. Courts have generally been disinclined to find a parent company, particularly, holding companies constitute an alter ego, because the subsidiary is not performing a function that the parent would, otherwise, have had to perform, itself.

Ex -- expressly stated in the affidavit, your Honor, is the fact that PLC is not involved in the day-to-day operations of INC. Rather, PLC's oversight authority entails approval of the most significant capital expenditures and strategy business decisions. That's something that we've offered up in our affidavits. Plaintiffs then in their response try to use that against us, but even one of the cases that plaintiffs rely upon and that's the In Re: Latex Gloves Product Liability litigation case says that:

> High-level strategic business decisions are precisely the type of matters one would expect a parent company to be involved in and they fall short of demonstrating that PLC is the alter ego of INC.

And -- and, in fact, that particular case, your Honor, says:

A parent may be involved in the -- quote -- monitoring -- of the subsidiary's performance, supervision of the subsidiary's finances and capital-budget decisions and articulation of general policies and procedures -- end quote -- without becoming its subsidiary's alter ego.

In sum, your Honor, I -- I don't think that, either the applicable law, either, as it pertains to the specific jurisdiction argument, the alter-ego theory or plaintiffs' requests discovery, coupled with the facts in this case, supports a finding of personal jurisdiction over PLC.

THE COURT: Very well. Thank you very much.

(Pause at 1:56 p.m.)

THE COURT: You're -- you're trying or making an effort here at bringing a parent company within the purview of this case and you have two compelling affidavits there, that demonstrate that this company has no contact, no design, no development, no testing, no manufacturing, assembly, promotion, package, label, they don't anything and they don't even sell in the U.S., it's the subsidiary company that is involved in this case, the subsidiary company admitted that.

So, tell me, factually, what are the facts that support your theory, that they have -- that PLC in this case -- has directed their activities at the forum state of

Pennsylvania?

MR. ASTRACHAN: Good afternoon, your Honor.

What I'd like to do is, I'd like to point out at the beginning, the specific things in the affidavit that we think demonstrate the type of control we're talking about.

THE COURT: In whose affidavit, the two affidavits that --

MR. ASTRACHAN: Susan Wabey's.

THE COURT: Okay.

MR. ASTRACHAN: For both the specific jurisdiction in this case and that based on the alter-ego theory.

So, in the affidavit, they say that they do have oversight, they have oversight over --

THE COURT: For what?

MR. ASTRACHAN: -- over strategic --

THE COURT: For that, that doesn't make -- that doesn't give you personal res -- personal jurisdiction --

MR. ASTRACHAN: Well --

THE COURT: -- of the -- of the company or this case.

MR. ASTRACHAN: -- well, they said that there's no common officers, like I said --

THE COURT: It's a parent company -- it's a parent company.

MR. ASTRACHAN: -- the common officers are completely shared. These press releases that they say only come from Smith

& Nephew, Inc., if you look at them, they tell you, specifically, they come from the holding company that has stocks in the New York Stock Exchange that she tries to minimize. They're the ones writing these press releases for the R3 metal liner, for the launch of the R3 System. All inquiries are directed to them. And they share common officers and directors.

The R3 liner that we're talking about and we point out in our brief was made in the United Kingdom. This parent is coordinating the activities of its subsidiaries and directing --

THE COURT: Why -- why do you want this company, a parent company in this case, when you have INC, who is the manufacturer, the designer of the system in this case, what's the point?

MR. ASTRACHAN: They hold responsibility for the injuries caused to my client.

THE COURT: You have a company here, right, that I suspect is sufficiently capitalized, right, to afford any -- any verdict -- should this case proceed -- any verdict that any jury will award, right?

MR. ASTRACHAN: Your Honor, I -- respectfully -- I don't think that that's relevant to this topic. I think we've brought them in, 'cause we --

THE COURT: Whether it's relevant --

MR. ASTRACHAN: -- think that they're responsible.

THE COURT: -- it's relevant or not, could you answer

my question?

MR. ASTRACHAN: Can you repeat it?

THE COURT: You have a capitalized company here, that can afford any verdict that a jury may award in this case, right?

MR. ASTRACHAN: I'm not -- I can't answer as to that.

THE COURT: Very well.

MR. ASTRACHAN: But I'd just like to continue pointing out some things that I've found troubling with what she said.

She told you earlier today that this company is not in the business of medical devices. Their own website in Exhibit A touts their global medical-technology business.

The trademark that she confirms exists is for medical devices in the United States. I don't think that that could be minimized when you look at the totality of the factors, you have to look at all of the activity that they've conducted. Their trademark is very important, if they hold it, they have the right to enforce these trademarks --

THE COURT: Where on Exhibit --

MR. ASTRACHAN: -- what --

THE COURT: -- where on Exhibit A, where it says, Smith & Nephew is in the global medical-technology business, does it say -- does it mention PLC, it's not there, is it?

MR. ASTRACHAN: No, it's not, your Honor, but I'd submit --

THE COURT: Right.

MR. ASTRACHAN: -- they haven't denied that that's their website. And I believe that that's their website --

THE COURT: It doesn't identify the PLC, it says, Smith & Nephew, doesn't it --

MR. ASTRACHAN: I -- I suppose it does.

THE COURT: -- and Smith -- and Smith & Nephew, Inc., which is the company involved with the manufacturing and production of the product in this case, sells in the international market, right?

MR. ASTRACHAN: I can't verify if that's --

THE COURT: Okay.

MR. ASTRACHAN: -- true or not, but --

THE COURT: But you do admit, it doesn't identify PLC --

MR. ASTRACHAN: I think --

THE COURT: -- right?

MR. ASTRACHAN: -- I can admit that.

THE COURT: Okay.

And on Exhibit F -- as she pointed out -- it doesn't identify it as PLC, it says, basically, Smith & Nephew, Inc., right?

MR. ASTRACHAN: No, I don't agree with that, when --

THE COURT: Well, let me read it to you --

MR. ASTRACHAN: -- look at --

THE COURT: -- let me read it to you:

Smith -- it's Memphis, Tennessee, San Francisco, California, March 6th, 2008:

Smith & Nephew, Inc., right, orthopedic reconstruction business today announced the global launch of the R3 Acetabular System, an advanced multi-bearing and Acetabular cup system used in total hip replacement procedures.

Doesn't it say that?

MR. ASTRACHAN: Right.

But let me point this out for a second. Do you see where it's says:

New York Stock Exchange, SNN, LSE, SN?

THE COURT: Okay.

MR. ASTRACHAN: Right.

When you look at Exhibit C, that's from the New York Stock Exchange website --

THE COURT: I --

MR. ASTRACHAN: -- and PLC's symbol is SNN.

THE COURT: All right.

I'm talking about Exhibit F --

MR. ASTRACHAN: And --

THE COURT: -- that you've produced, Exhibit F doesn't say, PLC, does it?

MR. ASTRACHAN: (No verbal response.)

THE COURT: You're reading another exhibit, I'm asking you about Exhibit F.

MR. ASTRACHAN: Right.

And on Exhibit F after it says, INC, it refers you to the New York Stock Exchange, SNN is the symbol. SNN is the symbol for Smith & Nephew PLC.

THE COURT: All right. And that's what you're relying on?

MR. ASTRACHAN: Well, that's the entirety of it, like, she spoke earlier, I think we're in agreement that this is a multi-factorial test for the alter-ego theory and for specific jurisdiction. You're inquiring for specific jurisdiction as to whether they purposefully direct --

THE COURT: What activity -- I want you to point me to one, two, three, four, five, six activities, that basically leads me to the conclusion that this company -- which is a parent company -- a holding company -- is directing their activities at Pennsylvania, so that you could assert personal jurisdiction.

MR. ASTRACHAN: Right.

Well, like I said when I started, they did re -- Exhibit D touts that they did research and development --

THE COURT: So, what?

MR. ASTRACHAN: -- to create new products.

THE COURT: So, what?

MR. ASTRACHAN: So, if you look at -- there's case law that shows that they -- and I'll find the specific -- the specific case is, Rockwell versus Custerzoni (ph), is one that they cited. There was a -- I am not exactly sure if it was a -- I think it was a parent company with a subsidiary, that they developed a product with the subsidiary to sell it within the United States and they found them subject to personal jurisdiction.

And it's because you can't just look at the exact moment at time of the sale, right. If they are doing research and development to develop these products, one of them -- the -- R3 medal liner -- that was implanted, they'll concede it's not even made in Memphis, it's made by another company in the United Kingdom.

They're -- they're developing all of these products and then, they have common officers. She didn't deny that the president of Smith & Nephew, Inc., is the same as a corporate director of PLC. They're coordinating activities between each other to then sell products within --

THE COURT: Where -- where do you get that?

MR. ASTRACHAN: -- the United States.

THE COURT: Wait -- that's -- that's an assumption that you're making, right?

MR. ASTRACHAN: I don't --

THE COURT: And one person that might sit on multiple

boards doesn't make it -- I don't think that's enough, but -- but go ahead.

MR. ASTRACHAN: Okay.

THE COURT: Where did you get this fact, that they're coordinating -- and I guess, conspiring is to -- to sell this product in the United States as -- as if PLC was INC as well, acting as if they were one?

MR. ASTRACHAN: Right.

Well, I'm going over all the things -- I'm sorry -- that we get interrupted, you know, the back and forth here.

But like I said, the press releases are directing inquiries to PLC for questions about the product's launch, for questions about the -- and when we speak about the product, I'm -- it's the R3 System's launch, we're not just talking about the liner and for the withdrawal of the liner. It demonstrates that there is intimate involvement between PLC and what is being produced and sold in the United States and when it's being recalled.

Their trademark registration, again, like I mentioned, the stock. And know that there's billions of dollars of revenue in the United States. They can't say that this was a one-shot kind of deal.

They cite to a case, McIntyre versus Nicastro, where personal jurisdiction wasn't found, but that was a case where the plaintiff didn't allege any control and there were a total

of four -- I'm not sure, exactly, what the equipment was -- but four machines, actually, entered the United States.

THE COURT: Very well. Anything else?

MR. ASTRACHAN: That's fine, your Honor.

THE COURT: Okay. Thank you.

Do you wish to respond?

MS. PETROWSKI: I -- very briefly, your Honor --

THE COURT: Go ahead.

MS. PETROWSKI: -- if that's okay.

(Pause at 2:06 p.m.)

MS. PETROWSKI: Your Honor, just very briefly.

You had asked plaintiffs' counsel to identify activities or conduct that was sufficient to confer personal jurisdiction. And I think that I've addressed most of the activities that Counsel mentioned. But I'd just like to run through a couple of them very quickly.

He talked about his assumption that PLC and INC were coordinating activities. In fact, the affidavits make it clear, your Honor, that PLC was not involved in the day-to-day operations of INC.

THE COURT: He's just -- he's asking me to ignore everything that is in the affidavit and look at the sparse pieces of evidence that they've produced to establish personal jurisdiction, that's basically their argument.

MS. PETROWSKI: The -- yes, your Honor.

The same with the -- the research and development piece, I mean, if you look at Exhibit C that's attached to their response, it doesn't mention PLC or INC, it doesn't mention the Acetabular System, the BHR System. It's a general page off the website discussing research -- research and development, generally. And from that plaintiffs' counsel contends that somehow, PLC was pouring all of this money in to the research and development of -- of these systems. But, again, that's directly refuted by the affidavits, themselves.

And, again, finally, plaintiff's counsel mentioned the press releases directing the inquiries to PLC. As we discussed in my arguments on our motion, itself, if you'd look at those press releases, the inquiries apply with equal force to representatives of INC as well.

THE COURT: Very well. I think I understand the arguments.

MS. PETROWSKI: Okay. Thank you, your Honor.

THE COURT: Thank you.

Let me move on to the motion pertaining to Smith & Nephew, Inc., the preemption issue.

MR. O'QUINN: Thank you, your Honor. Once again, I'm David O'Quinn. You probably recall that I was here back in March, because this --

THE COURT: Right.

MR. O'QUINN: -- motion that we're here on today,

arose, originally, from a 12(b)(6) motion that we filed in December. In that motion, we argued that the plaintiffs' claims were preempted, because the plaintiff alleged defects in a metal liner that has received PMA approval from the FDA and, therefore, the plaintiffs could not challenge the design or labeling that applied to that product and were relegated to showing a parallel claim, which we took the position then and take the position now, they have not done so with specific facts.

THE COURT: Okay.

So, let me -- so, let me, perhaps, focus in on some of these issues. The R3 metal liner -- as you just stated -- it's the only component that was used in Mr. Shuker's surgery and it's the only component part that received pre-market approval.

So, with that understanding would you agree with me that if plaintiffs' claim were based on defects in the other 5K clear components of the R3 Acetabular System, that claim would not be preempted?

MR. O'QUINN: No, your Honor, and let me first of all --

THE COURT: Why not -- why not?

MR. O'QUINN: Let me -- let me back up.

First of all, the shell -- although it's not material to the motion -- the shell was actually also part of the BHR System and cleared for it. But here --

THE COURT: The -- the --

MR. O'QUINN: -- here's -- but I'm glad you've cut to the chase, let me --

THE COURT: Okay.

MR. O'QUINN: -- let me -- let me get right to that.

THE COURT: This -- this --

MR. O'QUINN: They in their complaint --

THE COURT: -- is on metal, let's deal with that -- go ahead.

MR. O'QUINN: Yes, sir.

THE COURT: Go ahead, why don't you --

MR. O'QUINN: Thank you for the question, I -- I understand exactly where you're coming from and this is exactly what the court had to deal with in Simon and Bertini (ph).

THE COURT: Okay.

MR. O'QUINN: The R3 metal liner sits inside of a cup and a femoral component, okay.

The femoral component what it was approved for -- was a resurfacing component.

THE COURT: Right.

MR. O'QUINN: Dr. Terefenko said, I'm not going to use the resurfacing, I'm going to use a femoral component from over here, it's a viable use between the 510K femoral component and the PMA approved liner. Okay?

The Court's question as I understand it is, what if

they alleged a defect in other components --

THE COURT: In the other components.

MR. O'QUINN: -- and I have two answers to that.

THE COURT: Right. And not the -- the -- and not the metal liner, the R3 metal liner.

MR. O'QUINN: The first answer and the one that I think is -- is probably the most straightforward and the most dispositive is, they don't allege defects in the other components. And if the Court will --

THE COURT: But --

MR. O'QUINN: -- bear with me --

THE COURT: -- but -- but it -- your -- your point is, factually, they don't or they can't, because it's metal on metal, it was rubbing, right?

MR. O'QUINN: Metal on metal and rubbing, but their claims are contingent upon the liner and the fact that it's made of metal and the risks associated with that use.

They do not allege that any other component standing alone injured this plaintiff. And I don't see how they can allege that, given the fact that the only way these components are going to emit metal is by rubbing against the liner. And then Simon and Bertini --

THE COURT: From both sides, right, from both sides?

MR. O'QUINN: By both sides, the cup as well.

THE COURT: Right, right.

MR. O'QUINN: Yes.

THE COURT: So -- so, if I understand your position, it's that his claims -- the injuries, his claims -- are all directed in some way supposedly to the defect in the metal in the -- in the R3 metal liner?

MR. O'QUINN: No question about it.

And I've found my position in the notes, your Honor, this is in the briefs, but Paragraph 43 of the first amended complaint talks about:

> The metal liner would interface with or house the metal ball, femoral head component of the R3 Acetabular System.

It's not the R3 Acetabular System, but let's just use the fact, the liner interfaces with the ball.

> Because of this interface, the combination of metal components, the cobalt and chromium femoral head and the cobalt and chromium liner was and is referred to as a metal-on-metal bearing couple or a metal-on-metal system.

That's in Paragraph 43.

If you continue looking from Paragraph 43 through Paragraph 59, those are the specific facts as to what the plaintiff claims is defective.

He claims that the liner component -- not the other components -- the liner component was withdrawn from the market -- which it was -- because of a higher-than-expected revision

rate, meaning because it was rubbing against the people on those other components and releasing metal, it had to be withdrawn from the market. That's their allegation. They don't allege that the shell was withdrawn, they don't allege that the -- that the femoral component was withdrawn, they allege that the liner was withdrawn, because it was rubbing against the other components.

THE COURT: Well, what -- had they or if they allege defects in the other component parts that would not be preempted, you agree with that?

MR. O'QUINN: If we were writing on a blank slate, I might, but I don't see how you can plausibly say after filing an original complaint that said it was the liner, a first amended complaint that said it was the liner that goes into detail about what it is about the liner that causes these problems. And filing a motion to amend to file a second amended complaint, that goes into defects of the liner. I don't see how you can plausibly take that all back and now say, it's not the liner, it's --

THE COURT: Well --

MR. ASTRACHAN: -- something else.

THE COURT: -- but because they are claiming that the defects are with the liner, that has pre -- approval -- you claim that -- the argument is the claim is preempted?

MR. O'QUINN: Yes, your Honor.

And the -- and going a step further --

THE COURT: And --

MR. O'QUINN: -- the off-label use of the --

THE COURT: -- but I'm not -- I want to get --

MR. O'QUINN: Yes, sir.

THE COURT: -- I want to get to the off-label use later --

MR. O'QUINN: Sorry.

THE COURT: -- but I -- I want to understand from both sides' perspective, the complete argument on preemption --

MR. O'QUINN: May --

THE COURT: -- because the part -- the metal liner -- which was part of the other system, the BHR system, is the one that was -- that metal liner was used with the R3 Acetabular System for the hip replacement here, that the doctor used.

MR. O'QUINN: Correct.

THE COURT: Okay. I have questions on that.

But -- but the theory -- your theory -- is that because their claim is that the problem -- the defect -- is with the metal liner -- the R3 metal liner -- that automatically preempts it, because you have pre-market approval, it's not a -- a 360 -- a 5K clear component, it is a -- I believe, a 360 pre-market approval component, part of the BHR?

MR. O'QUINN: The allegations are, that the metal

liner by itself and rubbing against the other components --

THE COURT: Right.

MR. O'QUINN: -- released metal --

THE COURT: Right.

MR. O'QUINN: -- that caused Mr. Shuker pain and some disability and had to be taken out. That claim seeks to challenge the design and labeling for the liner component, because the FDA said, you can make it out of metal. And the FDA approved labeling which specifically cautioned the doctor not to use it -- well, they specifically, cautioned the doctor that it wasn't approved with this femoral component.

But Dr. Terefenko chose to do so -- I know you don't want to get into that yet.

THE COURT: Right.

MR. O'QUINN: So, but yes.

And if I may also add this, your Honor, before we leave this topic, just to make sure I alert you to it.

This is the same issue that the Simon and Bertini courts hit head on. Just as your Honor has done, those judges in the Southern District of New York said, wait a minute, there are other components and they weren't PMA approved, what does that do to you preemption argument?

And as in this case, the court said, look, everything you're saying depends on that liner, it all revolves around the articulation with that liner. And what you're complaining about

is the fact that the liner was made of metal.

And any -- I'd submit to your Honor and you can read the complaint -- any fair reading of the specific allegations of their complaint, their complaining about the liner. They're saying that the liner was made of metal, the liner released this stuff when it rubbed against the other thing, the -- we took it off the market, 'cause it wasn't working.

And the -- in Paragraph 59, they say:

> The pain caused by metal sensitivity due to the degeneration of the metal-on-metal articulation -- that's the liner rubbing against the other parts -- is why it had to come out.

THE COURT: All right.

MR. O'QUINN: So, and -- and --

THE COURT: Now --

MR. O'QUINN: -- the Bertini court said:

You can't separate the liner out.

And the Simon court said:

You can't separate the -- the liner out.

THE COURT: Now, to the extent that the plaintiffs are challenging the adequacy of the warnings accompanying the R3 Acetabular System, why isn't that -- why is that claim preempted according to you?

MR. O'QUINN: Your Honor, when we got the PMA approval, the FDA approved certain labeling for the device. It

had a surgical technique brochure and some instructions for use, which we've attached to the declaration of our regulatory manager, Gino Rouse (ph).

That labeling is the labeling and Smith & Nephew cannot change it, modify it or add to it without the FDA's permission. And unless and until the FDA says, change it, we can't change it. And a state law claim can't say, that we should have distributed any other labeling, other than the labeling the FDA approved.

And what they're saying is, you should have warned the doctor about using this device in some other way or you should have given him more information about metal sensitivity or something like that. But all of their claims are, basically, you should have told the doctor something different or in addition to what the FDA told you to say and they can't modify that labeling, that's our position.

THE COURT: Right.

Now, the documents that they have produced in support of their motion for leave to amend, suggest to me that the package insert for the R3 Acetabular System mentions R3 metal liners, which are not approved for use in the United States.

So, my question is, will their claim that the package insert will -- should warn -- that the R3 Acetabular System should not be used with the R3 metal liner be preempted?

MR. O'QUINN: The --

THE COURT: In other words, the R3 Acetabular System use in combination with the metal liner be preempted and why?

MR. O'QUINN: Your Honor, with all due respect, I don't think their arguing that the package insert said that.

What they did and what they attached to their motion to amend, was they attached the labeling for the poly liner, not the metal liner.

The poly liner doesn't mention -- excuse me -- doesn't mention the metal liner.

The Court may recall that when we were here in March, they had submitted the 510K documents for the poly liner. And they didn't have anything to do with the metal liner. Now, they're -- now, they're submitting the poly liner and saying that that's evidence of off-label promotion.

But if you'll look at it, it says on the front, poly, it's the poly liner, it doesn't say anything about the metal liner.

We attached to the declaration of Mr. Rouse, the FDA-approved information for the metal liner. And the metal liner, not only does it say, it's approved for resurfacing use, it specifically cautions the doctor -- twice -- that the resurfacing liner is not approved for use with the femoral component, except the resurfacing component.

In other words, it specifically says, it's not approved for the femoral component that Dr. Terefenko used.

So, with all respect, your Honor, I think that's a garbling -- what they're trying to do, is garble the record, because there's nothing in the package insert or in the FDA-approved labeling that does not fully and completely disclose the regulatory status of this liner. And we attached that labeling to the declaration of Mr. Rouse, which is un-controverted.

THE COURT: Very well.

In your -- in your motions, you also argue that preemption applies to the device, not the use of the device. For preemption purposes, what is the device in this case?

If -- if the device is the R3 metal liner, are there federal requirements applicable just to the liner?

MR. O'QUINN: Yes.

THE COURT: Or are there federal requirements applicable to the BHR System as a whole of which the R3 metal liner is a part?

MR. O'QUINN: Well, I think the Court asks multiple questions and I'll do the best --

THE COURT: Right.

MR. O'QUINN: -- I can to answer them.

In this case, I --

THE COURT: But all three go to the argument.

MR. O'QUINN: -- I don't know that there is a device. I think in this case, what you have is, you have a shell and a

liner that received PMA approval used off label with another femoral component. But the FDA cleared that liner as part of the BHR System.

And the plaintiffs' argument seems to be that, well, it was cleared as part of the system, so if it was used in some other way, it takes it out of that approval. That is incorrect and I think all of the case law is against that.

When the FDA approved our device, it says, you shall make it like this, you shall label it like that. We cannot put it into interstate commerce without doing what the FDA says.

In this case, we made it like the FDA said, we packaged it like the FDA said and Dr. Terefenko said, well, I see what you've got here, but I'm going to take this one off the shelf and match it.

And the case law is clear that that decision by the doctor to use it off label to use it off label does not defeat the requirements applicable to the device.

The Court also asked, were there requirements just for this component? Absolutely. And they're attached to the declaration of Mr. Rouse. We attached the -- some of the PMA approval materials to that declaration.

The liner had to be made of cobalt chrome, it had to be made of metal, it had to be made of metal of a certain alloy. It had to be distributed with certain packaging. There is no allegation that we didn't distribute it with the packaging that

was supposed to go with it, except this poly liner thing, which is obviously wrong and unsupported by any evidence and controverted by Mr. Rouse's affidavit, which has the correct labeling attached to it, which clearly discloses the regulatory status.

We had to --

THE COURT: Does it --

MR. O'QUINN: -- we had to make certain reporting obligations periodically to the FDA about the liner's use out in the field and what problems physicians may have been experiencing.

So, yes, sir, there were many and multiple requirements available to this component.

THE COURT: And regarding the warnings that must accompany the -- the R3 metal liner, which you complied with?

MR. O'QUINN: Yes, sir.

THE COURT: Okay.

MR. O'QUINN: There is a surgical-technique brochure and instructions for use attached to Mr. Rouse's declaration, which -- which was required by the FDA, that is the labeling we were required to give out with this device.

THE COURT: Separate -- approved separate labeling or packaging for the specific metal liner?

MR. O'QUINN: Yes, sir.

It's a -- a surgical-technique brochure for the R3

metal liner. The way this worked --

THE COURT: It's not just -- not -- not necessarily for the BHR System as a whole?

MR. O'QUINN: There were two. And I -- I think we only attached the surgical technique, but I think Mr. Rouse's declaration talks about both. The BHR System was approved first in 2007.

THE COURT: Right.

MR. O'QUINN: And there was a package insert and instructions for use for the BHR System.

We got a supplemental approval for the R3 liner. The FDA had a separate surgical-technique manual for that liner. Now, on the front -- it's attached to the declaration -- on the front it says, to be used in conjunction with the BHR System, blah, blah, blah, blah.

But it's separate instructions about how to use that metal liner in a resurfacing application with separate warnings and separate instructions for use.

So, the answer, sir, is yes. There were actually two in this case. One for the BHR System at first and a supplemental one for the liner component itself.

THE COURT: Separate warnings for the metal liner and they were inserted in the package?

MR. O'QUINN: Absolutely.

THE COURT: So, any -- any physician would be able to

know and understand that?

MR. O'QUINN: Well, I'm not a physician --

THE COURT: Well --

MR. O'QUINN: -- but I'm assuming that we --

THE COURT: -- they would have read --

MR. O'QUINN: -- I can answer it this way, the FDA told us to put it in the labeling and that's what we --

THE COURT: And it was there.

MR. O'QUINN: -- did.

THE COURT: Okay, okay.

This is separate and apart from the warnings and the instructions that were in the package for the BHR that were initially approved --

MR. O'QUINN: Yes, sir.

THE COURT: -- pre-approved --

MR. O'QUINN: Now, there is some overlap. I mean, obviously, the BHR System, some of the warnings were the same, you know, like the BHR said, this can cause metal sensitivity, you know, the BHR said, there's a metal liner literature out there, you might want to go look at it.

So, some of that stuff was in the -- in the package insert in the materials for the liner as well.

But if I understand your Honor's question, there -- there were separate requirements, including separate labeling for this component.

THE COURT: All right.

Now, to the extent that they challenged the adequacy of the warnings in the labeling for the R3 Acetabular System and not the BHR System or the R3 metal liner, why is that claim preempted?

MR. O'QUINN: Similar to what I've said before, the FDA told us, this is the labeling thou shalt use. And a state law tort claim cannot add to or modify that labeling.

The plaintiffs, in essence, are saying that, you should have told the doctor more about metal sensitivity or you should have told him in more un -- you know -- stronger that he shouldn't use it off label. They're saying something.

But whatever they're saying, it's in addition to or a modification of that labeling, which we cannot do and Section 360(k) says, a state law tort claim cannot do.

THE COURT: Right.

I wanted to move on to the off-label promotion and parallel claims --

MR. O'QUINN: Yes, sir.

THE COURT: -- unless you have anything else to add to the questions I've posed. I -- I try to get pointed questions, so that I could understand the preemption argument --

MR. O'QUINN: I -- and I appreciate --

THE COURT: -- a little bit better.

MR. O'QUINN: -- it, your Honor, I mean, you can

always read the brief. I'm glad to know what's on the Court's mind and now, hopefully, I've at least answered to you as to what our position is.

THE COURT: All right.

Now, moving on to the off-label parallel claim.

It seems to me that -- it seems to me -- and the Ramirez decision has been heavily criticized and you disagree with it. But it seems to me that despite the fact that you disagreed with that decision, you agree or acknowledge that the promotion of off-label use in some circumstances can support a parallel claim.

So, my question to you is -- and you could tell me if I'm wrong in that assertion -- but would you agree, for example, that if the claim were that Smith & Nephew made misrepresentations about the safety of the R3 metal liner for use with the R3 Acetabular System, that that claim could not be preempted?

MR. O'QUINN: If we agree with the Court, that if the plaintiff could show specific facts demonstrating that we violated federal law in the promotion of this device in such a way as to mislead Dr. Terefenko to use it, that could potentially be a non-preempted parallel claim.

THE COURT: Okay.

Is your argument, essentially, that they have not adequately pled a parallel claim, based on off-label promotion,

even in their second amended complaint?

MR. O'QUINN: Absolutely, that's our argument.

And if the Court will permit me --

THE COURT: Go ahead.

MR. O'QUINN: -- if you go back to the first amended complaint, you may recall that they wanted to depose Dr. Terefenko and we had the discovery issue.

And part of our opposition to that was that Dr. Terefenko -- there was no allegations that they had promoted off label to him and the Court agreed with that. And said, you're right, I'm not letting you depose Dr. Terefenko, because they haven't pleaded a claim for off-label promotion.

Be that as it may, if you go to the second amended complaint which they say is necessary now that they've done all of this discovery, there is not a single specific fact showing any violation of any federal law that led Dr. Terefenko to use this device.

Now, I can go through what they say real quickly, if you'll let me, your Honor --

THE COURT: Go ahead, I will.

MR. O'QUINN: -- and there's four things.

First of all, they have a press release that accompanied, the -- the release of the product and they seem to say, well, it talked about its use in the R3 Acetabular System and that's confusing and, therefore, it's off-label promotion.

Well, first of all, the FDA approved the name, R3 for this component, okay. So, I don't see how you can violate federal law by calling it, the R3, when that's what the FDA called it.

But, number two, that press release which was in their original complaint, their first amended complaint and their second amended complaint, discloses the regulatory status in the second sentence and I attached it to the opposition, it says:

It was recently --

I'm paraphrasing.

-- but it was recently cleared for use with the BHR resurfacing system.

The second sentence of the press release discloses the regulatory status properly. So, that's not a violation of federal law. And they don't allege that Dr. Terefenko even saw it.

The second thing they do, is they attached the poly label. The question your Honor has about the package --

THE COURT: Right.

MR. O'QUINN: -- insert. That's just wrong. It's wrong, it's the poly liner, the correct labeling is attached to Mr. Rouse's affidavit.

And we gave Mr. Rouse's affidavit to them as part of the discovery process that the Court allowed. We probably weren't obligated to, but we said, look, here's the affidavit

we're going to submit with our summary judgment. They never asked to depose him, they never came back and controverted it.

The un-controverted evidence in this record is that the labeling attached to Mr. Rouse's declaration is the labeling, period.

And this poly liner on its face doesn't say anything about the metal liner, it's the poly liner.

So, that's the second thing, so that doesn't show a claim.

They also say, separately, that the R -- that we called it the R3 and that was misleading. Well, the R3 -- the FDA approved that name. That's the FDA-approved name, the R3.

And then, finally, they cite an operative note from Dr. Terefenko, where he talks about a metal-on-metal articulation being appropriate for this patient. That operative note doesn't say anything about Smith & Nephew. It doesn't say anything about the liner. It doesn't say anything about any representations made to him. It doesn't say anything about any materials we gave him that misled him. It just says, that he was going to use a metal-on-metal system.

There were a bunch of metal-on-metal systems in the market, we don't know why he decided to do that. We don't know how he came to that decision.

But what is clear is the plaintiffs' complaint does not allege any specific facts showing that Smith & Nephew

violated federal law and induced this doctor to use it.

On the other side of the coin, the labeling -- the FDA-approved labeling attached to Mr. Rouse's declaration says, twice, that it's only approved with a resurfacing component, it says, this is the liner for the BHR resurfacing system and, oh, by the way, Doctor, the only cleared femoral component is the resurfacing component. And I've cited that to your Honor in the briefs several times, it's attached to the materials we've submitted. So, that's it.

They're saying, Court, let us have another bite at the apple, because we've got these facts that show that we promoted off label. But the specific things they point to don't show that.

I'd also like to add, your Honor, we do agree that in appropriate circumstances an off-label promotion claim could go forward, but there's not one here, that's, basically, our position.

And that law shows you why their other arguments are wrong. They're saying that if the FDA approved it as a system and the doctor took it off the shelf and used it some other way, then that approval goes away somehow. But how can that be? We don't know how the doctor is going to use it when we put it on the market. We -- you know -- our obligation is not to fraudulently make him use it off label. So, the FDA can't regulate that ultimate use.

What it does regulate and what the cases that I've cited to your Honor about the Ramirez case, particularly, say is, the manufacturer can't violate federal law in promoting the project -- product -- to the doctor. If he does that, you don't get preemption.

Now, we disagree on the scope of that, but that fits in perfectly with the overall regulatory system, you'd go to the FDA, you'd get your clearance. The FDA tells you how to label it. You put it out in the world.

If doctors begin to use it off label, we're not responsible for that, unless we've violated federal law in the way to get them to use it that way. And there are not specific allegations on that.

THE COURT: Well, they -- in their amended complaint and in the first complaint, they've -- on the parallel claim -- they brought a whole bunch of violations of federal law. One of the problems was in getting -- connecting the dots and showing how those violations led to the injury.

Does the amended complaint change analysis on the parallel claim?

MR. O'QUINN: It does not, your Honor, because of two reasons:

They did cite a lot of federal law. And if you'd look at some of the specific things they've cited, it's -- it's all along the lines of Smith & Nephew violated CFR such and such and

CFR such and such in failing to properly label the device.

Smith & Nephew violated CFR such and such and such and such in improperly distributing the device or improperly manufacturing the device.

There are not specific facts in both the first amended complaint and the second amended complaint, they just went to the Code of Federal Regulations and they paraphrased the elements of some kind of violation and said, aha, we've pled a parallel claim. The case law resounding rejects that.

I mean, if you'd look at the specific facts, where are the specific facts that show that we violated federal law and as a result of that violation, Mr. Shuker did not get the liner as approved by the FDA or the labeling approved by the FDA? There's no specific facts.

What they point to in their motion to amend are things that clearly don't do that, the poly liner, a press release that discloses the regulatory status, an operative note the doesn't say anything about anything, that's their evidence, your Honor, and that doesn't plausibly show an off-label promotion claim.

THE COURT: Very well.

Anything else with regards to your arguments?

MR. O'QUINN: Thank you for the opportunity, your Honor and let me just see if there's --

(Pause at 2:34 p.m.)

MR. O'QUINN: Your Honor, we've briefed this several

times. Your Honor's questions show to me that you're on top of it. If anything comes to you while we're going through this process, I am glad to be here and appreciate the Court's attention and the opportunity to answer anything you have, just let me know what else, you may want to --

THE COURT: Very well.

I'll give you an opportunity for rebuttal after I hear from the plaintiff.

MR. O'QUINN: Thank you, your Honor.

(Pause and whispering held off the record.)

THE COURT: Mr. Zajac, I want to talk about the use of the metal liner and the -- with the metal femoral head, okay?

MR. ZAJAC: Right.

THE COURT: And my question to you is the following:

Is it correct -- or is it a correct interpretation or reading of your complaint, that Mr. Shuker's injuries were caused by the metal-on-metal articulation as reflected in the notes of the components used in the hip replacement -- replacement?

MR. ZAJAC: I -- I believe that it is an overly-narrow, unreasonable interpretation of the complaint to say that, the defect is limited to the metal liner. I don't know if that answers your question.

THE COURT: Well, we have the cup and we have the metal liner and they were rubbing, right?

MR. ZAJAC: Correct.

THE COURT: And that's what caused the injury, if any that he had, right?

MR. ZAJAC: That's what caused -- probably, caused the metal-on-metal release.

THE COURT: Isn't that what caused the problem?

MR. ZAJAC: There are -- there are multiple problems, that caused one of the problems, based on the limited record we have available and that is the operative report from removing the materials, is that those two items --

THE COURT: Well, hold on a minute -- hold one a minute.

MR. ZAJAC: Yes.

THE COURT: I just asked you a simple question, your answer is that my interpretation of your complaint is too broad or too narrow, right?

MR. ZAJAC: In that limited respect, yes.

THE COURT: All right.

Do you have any claims that the hip-replacement system that he received was defective or unsafe, independent of the metal liner?

MR. ZAJAC: Yes.

THE COURT: Independent of the metal liner?

MR. ZAJAC: With respect to warnings, I believe so, yes.

THE COURT: In other words, are there any claims in your complaint that don't depend in some way on the metal liner -- on the metal liner?

MR. ZAJAC: The metal liner is, clearly, a part of it.

THE COURT: It's the central part of your case, isn't it?

MR. ZAJAC: No.

THE COURT: Okay.

MR. ZAJAC: Okay. Let me --

THE COURT: Go ahead.

MR. ZAJAC: -- and let me ex --

THE COURT: What's your argument?

MR. ZAJAC: -- let me also say this, that even if it were -- let's assume for argument purposes that --

THE COURT: You admit that the metal liner had pre-market approval, we go that far, right, your initial argument before was of -- right?

MR. ZAJAC: It had qualified approval and that's really super important.

THE COURT: A qualified approval?

MR. ZAJAC: Yes.

Because when the FDA approves a component part, okay, it always does so in the context of the hip system that it's part of.

THE COURT: Qualified.

You're just seem to be shifting your -- be shifting your argument from the motion to dismiss to now -- to your brief to now qualified approval.

MR. ZAJAC: I --

THE COURT: Did it get pre-market approval or not?

MR. ZAJAC: It got pre-market approval as a component for use in the BHR with BHR femoral components. It did not get PMA approval.

THE COURT: Where do you get that, what -- where -- where did you get that --

MR. ZAJAC: From the P --

THE COURT: -- is that --

MR. ZAJAC: -- from the PMA record for -- for the -- for the --

THE COURT: Tell me where -- where does it say that they got qualified approval, that it could only be used -- what I understand you are saying is, it could only be used with the BHR System, right?

MR. ZAJAC: Okay. All right.

THE COURT: Is -- is that your argument, is that --

MR. ZAJAC: Absolutely.

THE COURT: -- what -- am I understanding it correctly --

MR. ZAJAC: Absolutely.

THE COURT: -- that it could only be used with -- with

that system?

MR. ZAJAC: Absolutely -- absolutely.

I apologize for turning my back on you, I will have to go back and get my binder.

THE COURT: Okay, go ahead.

MR. ZAJAC: Okay.

(Pause at 2:38 p.m.)

MR. ZAJAC: Now, let -- let me just point to, generally, there is a section in my brief that cites to various Bates numbers, okay, that were produced by Smith & Nephew, where Smith & Nephew when it applied for the BHR supplement for the metal liner, it specifically said, we're not changing the articulation with the femoral heads. Okay.

They went to great lengths to represent to the FDA, we are not changing the articulation with the femoral components. The BHA has its own special femoral components and we -- we cite what they are in our brief when we cite to the Bates numbers.

And when Smith & Nephew applied for the supplement it said, we're going to be using the same femoral components, no other femoral components and, therefore, there's no -- no change in safety or effectiveness.

If you want to, I can try to go back and find my brief, where I cite to those Bates numbers. We know from -- we know from Bates No. 12535, that the FDA reviews hip systems and not individual components.

THE COURT: All right.

MR. ZAJAC: And when it does so, it wants the manufacturer to identify the entire system of components under review for that system.

THE COURT: Okay. So --

MR. ZAJAC: Okay?

THE COURT: -- so, let me see if I understand, maybe -- maybe -- I think this goes to your argument that I should look for purposes of the preemption analysis at the device as a whole and not at the component parts in conducting my -- my analysis, right?

MR. ZAJAC: Correct.

THE COURT: You also seem to be arguing that the device at issue in this case is the Class 2 5K clear system, right?

MR. ZAJAC: Correct.

THE COURT: But isn't it true that the FDA has never approved the 5K review or pre-market approval process, the particular device used in his surgery?

MR. ZAJAC: In that particular assemblage, correct, it did not --

THE COURT: Right.

MR. ZAJAC: -- and that has important implications for preemption.

THE COURT: And doesn't this fact, that the precise

combination of components used in Mr. Shuker's surgery had not been approved, distinguish this case from the cases cited in your brief, regarding 5K clear components that are later incorporated into a device that receives pre-market approval, it makes a big distinction, doesn't it?

MR. ZAJAC: I -- I disagree that it does and let me explain, okay?

THE COURT: Okay.

MR. ZAJAC: The particular assemblage of components here, is not part of a true device that has been reviewed by the FDA in that particular assemblage, right, we -- I think we can agree that the FDA never looked at this particular use of components and said, we will give this our blessings, it's fine.

The -- the FDA -- the regulatory system has a default and the default is this, if you have a -- if you have a hip system that has not undergone any specific review, it is by default a Class 3. However, it's not Class 3 that invokes preemption, it's MDA approval that invokes preemption, okay.

So, what you have is a Class 3 device by default that has never been MDA approved.

And if you look at Section 360 and all the cases that talk about preemption, the idea behind preemption is that the manufacturer got approval, you -- you submitted -- you submitted the -- you identified all the component parts, you identified -- you sent in all your studies, you answered all of the questions,

you went through all the clinical trials and the FDA said, you can go ahead and sell. That's what entitles you to preemption, not just being a Class 3 device.

In fact, part of what we allege --

THE COURT: To get to be a Class 3 device, so you have FDA approval, is part -- one of the most vigorous processes that you have to go through to get that -- that classification, right?

MR. ZAJAC: I'd -- in a word, no, because if you do not get -- if you do not get MDA approval, you are considered Class 3 by default, all right.

In other words, you have -- you have sold something that has never undergone the rigorous review, that makes it Class 3.

What that does importantly, is it invokes the requirement -- any manufacturer selling a Class 3 system -- has to get MDA approval and identify all the component parts. It's a distinction with a difference. Okay.

So, the end -- the end result is the same here and that is that they're not entitled to preemption.

So, either -- either, it's a Class 2 510K cleared system with a single component part from another Class 3, PMA approved system or it's not really a system at all, it's by default, Class 3, but it's Class 3 not PMA approved, so it's not entitled to preemption.

THE COURT: Very well.

So, you're saying although the metal liner in this case was approved as part of the -- of the BH -- BHR resurfacing system, that -- that that device was approved, not necessarily, the component part and when you use it with the R3 Acetabular System, that is a Class -- that becomes a Class 2 device?

MR. ZAJAC: I -- I don't think that you can change the Class 2 status of the R3 Acetabular System. just by taking the metal liner and using it with it, that -- that in fact, there incredible policy considerations there.

THE COURT: But you agree that the R3 metal liner received pre-market approval?

MR. ZAJAC: For use with the BHR with BHR femoral components.

THE COURT: But it is a component part of the BHR System that got pre-market approval?

MR. ZAJAC: For that use, yes.

THE COURT: It had -- it had a package and it had instructions to be used by itself, didn't it?

MR. ZAJAC: Let's talk about the -- the packaging instructions, because I think there has been a lot of confusion about that, okay.

Let's talk about the surgical technique documents that have been referenced. And there is a surgical technique document --

THE COURT: So, it did not have any warnings that the component part, itself, had no packaging or warning that any physician would be able to access and read it?

MR. ZAJAC: The liner did.

THE COURT: All right.

MR. ZAJAC: The -- the --

THE COURT: As pre -- as it had -- as consistent with the pre-market approval?

MR. ZAJAC: Correct.

THE COURT: Okay.

MR. ZAJAC: Correct.

Now --

THE COURT: So, what's the problem with that?

MR. ZAJAC: Okay.

There's -- there's many problems with that.

Number one, okay --

THE COURT: It tells people how to use it, right, it tells doctors how to use that device, that metal liner --

MR. ZAJAC: They're --

THE COURT: -- which is a component part of the BHR -- the BHR System, right?

MR. ZAJAC: Yes. Okay.

It -- it's -- but they're -- they're doing one thing with their left hand and doing another thing with their right hand.

With their left hand, they're giving you a little insert with the liner that says, this is approved for use with the -- with the BHR. Okay.

And then, on the other hand, they're encouraging the doctors to go off label.

THE COURT: How? What facts do you have, that they are doing that --

MR. ZAJAC: Okay.

THE COURT: -- other than they're making the product?

MR. ZAJAC: Considering, I haven't had discovery on that, I have a pretty good set of facts and I --

THE COURT: Okay.

MR. ZAJAC: -- and I'd point out we have only had discovery on the regulatory status of the device, not on its marketing and distribution.

So, your Honor, please understand, I'm only going by what I have inferentially and from indirect sources. I have not had discovery on this.

But here's -- here's what -- you know -- here's what we know.

We know that, first of all, they called it the R3 metal liner, all right, they didn't call it the BHR metal liner, they --

THE COURT: They said, FDA called it the R3 metal liner.

MR. ZAJAC: Absolutely wrong. The FDA does not approve names, okay, that is -- that is such a mis-directional argument.

The FDA doesn't say, we are allowing you to call this the R3 metal liner, because we think it's okay to call it that. They do not regulate the name. Okay. So, that's number one.

We -- we know, in fact, that the FDA has specifically told us in response to a subpoena, that it was never -- they didn't even know it was called the R3 metal liner, it was never approved for use with the R3 Acetabular System. So, they call it that.

As soon as -- as soon as the -- the metal liner was approved through the supplement to the BHR, almost immediately, Smith & Nephew goes out and tells all the doctors, we now have this optional metal liner and they -- they call it the RD Acetabular System optional metal liner. All right. That's what they call it all over the place. Okay.

And they have these surgical --

THE COURT: I --

MR. ZAJAC: -- techniques -- these surgical-technique documents and these are Bates Nos. 13167 onward, is the one for the R3 system. These surgical-technique brochures, your Honor, are not for the liners, they're for the procedures. Okay. They're for the procedures.

The -- the one that begins at 13167 goes through and

explains the entire procedure for the R3 hip replacement, okay. The -- the liner is not on this first page, you see, the first page here, if I could direct you back to the beginning.

THE COURT: I have it.

MR. ZAJAC: It -- it does say, poly, but it doesn't use the word, liner and the picture is not of the liner, it's of the shell.

THE COURT: Right.

MR. ZAJAC: All right.

And then, you go through and any reasonable reading of this pro --

THE COURT: They -- they argue, you're wrong, that this is not pertaining to the metal -- the R3 metal liner.

MR. ZAJAC: Well, they argue a lot of things that are inconsistent with -- with the record and things that they say in other documents and this is one of them, because nowhere --

THE COURT: It says, poly, right, it doesn't say, metal liner?

MR. ZAJAC: They've used the word, poly, but it doesn't say, a liner.

THE COURT: All right.

MR. ZAJAC: And it's -- and it's a picture of the shell and -- and it says, surgical technique, no hole, three hole, multi-hole, pre-operative planning, short technique, it goes through shell and liner offerings, it goes on and on and

on. It doesn't say that it's specific to the liner.

And here's to the point of your Honor -- your Honor is asking a question about, well, what about the components that are not part of the PMA approval, what about these other R3 parts?

There's nothing in here that says, you cannot use the metal liner in this procedure. In fact, the language is ambiguous.

On Page 9 of the document, itself, where it gets into the R3 Acetabular liner insertion, it uses -- the terms, XLPE, it uses the term R3 Acetabular liner. It's not -- there's nothing in here that says, you can't use the metal liner for this procedure.

And then, you go back to the other surgical-technique document that they're relied upon, that this one (indicating).

THE COURT: All right.

MR. ZAJAC: And they -- I'm sorry.

THE COURT: That's the --

UNIDENTIFIED COUNSEL: Thank you.

THE COURT: -- that's the (indiscernible) and the hip, right?

MR. ZAJAC: Right.

This is the one that says --

THE COURT: These are two different things, are they not?

MR. ZAJAC: That's my point. My point is --

THE COURT: Go ahead.

MR. ZAJAC: -- they're very different things, because the -- Smith & Nephew's counsel cites to this and says, this says:

> Don't use the metal liner with the -- with anything else, other than BHR.

But Dr. Terefenko, why would he be looking at this, if he's doing -- he's not doing a BHR. Okay.

So, they point to this and they say, your Honor, it says right in here, you know, you're -- you're not supposed to use this for anything, other than -- ah -- than the BHR.

And it says in here that:

> In the U.S., the metal liner is intended for use as part of use as part of the BHR system only.

Okay, great. But Dr. Terefenko is not putting in a BHR, he's doing a hip replacement.

So, if he's looking at anything, he's looking at the first one I gave you and there's nothing in there that says, oh, you'd better not use -- you'd better not use the metal liner, you can only use the poly liner. Okay.

So, let's -- let's try to -- you know -- let's try to clarify that. Okay.

I have -- I have a few other points that I'd like to make here.

There were a lot of remarks about the declarations that were made by the Smith & Nephew folks. Those declarations were served almost at the very end of the discovery period. I had no opportunity to depose them. It's not like they were given early on and then, I decided, I didn't want to depose them, they -- they were given three or four days before the discovery-end date. And a lot of representations were made that I could have deposed them. I had no reasonable opportunity to do so.

THE COURT: The fact that they filed an affidavit in support of their motion, even if you had deposed them and you didn't review the questions that were relevant, they had the opportunity to file an affidavit in -- in support of the motion for summary judgment and you had an opportunity to submit a counter affidavit, right?

MR. ZAJAC: Ah, I'm not sure from whom I would be able to submit a counter affidavit.

THE COURT: Very well.

MR. ZAJAC: I -- I did try to take Dr. Terefenko's deposition.

Okay, let me --

THE COURT: Okay.

MR. ZAJAC: -- let me go back to some of these points about --

(Pause at 2:53 p.m.)

MR. ZAJAC: Okay.

You asked the question, your Honor, what exactly is the device?

THE COURT: Correct.

MR. ZAJAC: We have submitted the information from the FDA, itself, directly that says:

We review systems, not individual components.

That's Bates No. 12535. Okay. Why is --

THE COURT: So, what is the system --

MR. ZAJAC: The system --

THE COURT: -- according to you, that caused the injury?

MR. ZAJAC: It is an R3 Acetabular system that is using an R3 metal liner, but that does not allow preemption, simply because the R3 metal liner was used.

I -- obviously, the R3 metal liner was used and the R3 metal liner is from the BHR, which was PMA approved.

THE COURT: Which is a component part of the BHR -- the Birmingham Hip Re -- Resurfacing which got pre-market approval.

MR. ZAJAC: Correct.

So, let's -- let's --

THE COURT: And the -- and the component part, you will agree got pre-market approval?

MR. ZAJAC: For the BHR, yes.

THE COURT: All right.

MR. ZAJAC: Let's -- let's talk about the policy argument, I made before. Okay.

What is the defendant asking the Court to do? We have --

THE COURT: See, you're -- you don't have -- it seems to me that -- and I get back to this -- this whole question -- you don't have an independent claim from the metal liner, you don't -- you don't -- standing on its own, somehow, the metal liner is connected or interconnected with the Acetabular System, that you have the R3 Acetabular System that -- that was used. It's not independent, it's part --

MR. ZAJAC: It --

THE COURT: -- of whatever -- whatever occurred, 'cause it was metal on metal, you cannot stand on your own, it's not an independent claim which you -- which, I think, they agree, it would have been preempted.

MR. ZAJAC: Well, yeah -- yeah, but let's talk about that.

I agree, your Honor, you can't have metal-on-metal debris, unless you have the metal liner in contact with other metal, okay. Correct.

But, please, consider this, if there's any point you take away from this argument today, it is that that particular metal-on-metal articulation with the -- with the BHR metal liner

with the R3 femoral components, it was never looked at by the FDA. They're different femoral components.

THE COURT: You're not -- you're not complaining the R3 Acetabular System by itself was the problem, right?

MR. ZAJAC: In and of itself without there being a metal-on-metal liner, correct.

THE COURT: Okay.

MR. ZAJAC: But my -- but my point is, it doesn't -- here's -- here again, is my policy point, okay. You have -- I think we agree we -- we have an otherwise, 510K cleared system, if we'd take the metal liner out, right and we use a poly liner, then everything is 510K cleared. I think we all agree with that. The system is 510K cleared, it's all -- it's all 510K, which means there's no preemption, right?

Think of the policy position here. If you can -- if you were a manufacturer, like, Smith & Nephew and you have a component from a different system which has been vigorously studied and reviewed that has different metal-on-metal articulations between Acetabular and femoral and you pull that out and you stick it in a Class 2 510K cleared system, you have just turned that 510K cleared -- 10 -- I'm sorry. You've just turned 510K cleared system into a PMA approved system.

You've completely circumvented the whole point of getting PMA approval -- completely. That's the next step of this -- that's the next step, you've completely undermined the

entire PMA approval process.

THE COURT: But the system that you've got -- got, neither, 5K -- no pre-market approval, right, neither one?

MR. ZAJAC: Correct.

THE COURT: Right.

MR. ZAJAC: So, it's --

THE COURT: Doesn't --

MR. ZAJAC: Yeah.

THE COURT: -- that -- the fact that it was using a combination of -- those two component parts were using a combination in the surgery that had not been approved, distinguish the situation here from the cases you've cited in which 5K cleared components are later incorporated into the device that received pre-market approval?

MR. ZAJAC: In that -- that -- that is a way to look at it, yes.

THE COURT: Okay.

MR. ZAJAC: But again, under the scheme, that makes it Class 3, but not PMA approved and because it's not PMA approved, you don't get preemption.

THE COURT: Okay.

MR. ZAJAC: So, you still land with no preemption under that analysis.

THE COURT: Very well.

Assume for a minute that Smith & Nephew did not

promote the R3 metal liner for use with the RE Acetabular System, but merely had the metal liner on the market for use in the BHR System, make those assumptions.

If that were the case, why shouldn't the company get the benefit of preemption, when a doctor decides to put the metal liner off label used with the R3 Acetabular System?

MR. ZAJAC: If -- if -- if the manu -- right.

THE COURT: In other words, shouldn't the device make or get the benefit of preemption, so long as it is only promoting its device for users approved by the FDA?

MR. ZAJAC: Under -- under that limited factual scenario, which I don't believe we had, I would pack up my bags and go home.

THE COURT: Okay.

Why not -- why don't you think you have those limited circumstances here?

MR. ZAJAC: Well, because we know based on a rather limited record, that through the press releases that are -- that are in the record -- and I apologize, I can't quote them verbatim -- okay -- that once -- once the metal liner was approved, a press release was issued by Smith & Nephew, either, directly or indirectly, encouraging surgeons, like, Dr. Terefenko to use that metal liner in the R3 System.

We -- okay -- we know -- we know that it was being called the R3 metal liner. We know inferentially from the

recall notice, it has language in it that is a clear concession that Smith & Nephew has been putting this product out there, as if it's part of the R3 System.

And if you want me to quote that, I can find that, but it's pretty -- and excuse me for saying this -- pretty damning language that indicates that Smith & Nephew is -- is regarding this device as part of the R3 System. Otherwise, it's hard to imagine, how they worded the recall notice the way they did.

THE COURT: All right.

MR. ZAJAC: That's some of it and again, this is without the benefit of formal discovery and this will -- I think -- brings us back to the Cullen (ph) case.

I can't possibly prove my entire case in my complaint. If your Honor wants that degree of factual specificity, I'd be happy to provide it in a pretrial memo.

THE COURT: Very well.

Let me -- let me move on then.

To the extent that they are claiming that the R3 metal liner was negligent -- negligent or defectively designed -- doesn't the fact that it was PMA approved or received approval as part of the BHR System, prevent the company from changing the design of the R3 metal liner which is part of the BHR System?

MR. ZAJAC: No. In fact what you're supposed to do if you're Smith & Nephew, if you're --

THE COURT: No? You have -- you're not -- you're not

prevented from -- from changing the design or adding to the design --

MR. ZAJAC: Not -- you -- you have --

THE COURT: -- without -- without FDA approval?

MR. ZAJAC: You have to go back to the FDA and say, FDA, I want -- I want doctors to use this metal liner with the R3 Acetabular System, let me show you why it's safe and effective to do so. That's what you are supposed to do under the regulatory scheme.

And that's what I refer to as the inconvenient truth in my brief, about why the defendant continues to glob on to the fact that the liner, itself, was PMA approved.

Because the regulatory scheme says, you really are supposed to be going back and telling the FDA that this is being used for a purpose -- for different femoral components, because you told the FDA when you submitted this for approval that you were -- that there was going to be no change in the femoral components, that they were going to be exactly the same as they were before. And we know that they are, in fact, different. And we know that it's at that juncture, that Dr. Terefenko found significant metal debris.

THE COURT: Very well.

In your complaint, you brought certain claims for a breach of expressed warranty in which you are claiming that the defendants expressly warranted that the R3 Acetabular System and

the components, which is the R3 metal liner, foreseeably, would be used when it was safe and/or well accepted by users.

And my question is, is it a correct reading of your complaint that you are not alleging that the defendants expressly warranted that the R3 Acetabular System was safe for use with the R3 metal liner, you're not claiming that, right --

MR. ZAJAC: The --

THE COURT: -- you are not --

MR. ZAJAC: -- they didn't expressly --

THE COURT: -- claiming --

MR. ZAJAC: -- use those words.

THE COURT: Hold on a minute.

MR. ZAJAC: All right.

THE COURT: You are not claiming that the defendants expressly warranted in any way, shape or form, that the R3 Acetabular System was safe for use in conjunction with the R3 metal liner?

MR. ZAJAC: In a breach of warranty context, that's -- that's correct.

THE COURT: Okay.

Well, let's move on to the preemption. If you -- if you have anything else to add -- to add to the off-label promotion, if you have any things to add to the preemption argument, are you done?

MR. ZAJAC: Let me -- if I can just take a moment to

look at my notes, I believe, I am but I just wanted to be sure.

(Pause at 3:03 p.m.)

MR. ZAJAC: I just have one final thought on that and I -- I promise I -- we can move on to the next issue.

I cite the Regal case, the U.S. Supreme Court case in my brief as to why defendant manufacturers get the benefit of preemption and -- and the whole principle behind it, is because the device, its components were tested and vetted and analyzed and found safe.

I am not asking the Court to find this product or device be made safe for any -- in any way different from or in addition to what the FDA looked at when it approved this liner.

THE COURT: Right.

MR. ZAJAC: It approved this liner with a very specific set of femoral components, not the set of femoral components that was used.

Okay, off label --

THE COURT: All right.

So, help me out here in -- and I want to focus on the off-label promotion and then I want to focus on Count 2 and your amended complaint.

First of all, if I conclude the preemption applies because the R3 metal liner received pre-market approval.

And further, if I conclude or decline to follow Ramirez which has been heavily criticized and not even followed

in its own district court, such that you are limited to a parallel claim, based on off-label promotions -- so, I'd make those assumptions -- what is your parallel claim based on promotion of label uses, what is it, factually? What is your theory -- factual and legal theory -- with regards to your claim as to promotion of off-label uses?

MR. ZAJAC: Okay.

Well, I'm just finding where this is in my proposed second amended complaint.

(Pause 3:05 p.m.)

MR. ZAJAC: And Count 2 is Paragraphs 126 onward.

THE COURT: In other words, what I want to get at is -- because you went through twenty pages in your second amended complaint. But what I want to get at is for you to very succinctly tell me, what -- what is the factual basis for your claim that Smith & Nephew promoted the R3 metal liner for use with the R3 Acetabular System to doctors in the United States?

And what theories are you pursuing with respect to off-label promotion?

MR. ZAJAC: Okay.

THE COURT: In other words --

MR. ZAJAC: Right.

THE COURT: -- give me the meat or your factual and legal theory.

MR. ZAJAC: Right.

Here's the gist of it then. After the R3 metal liner was approved with the BHR, Smith & Nephew issued a press release, okay, communicating to physicians like Dr. Terefenko, that you now have this metal liner to use as an option with the R3 Acetabular System. Okay. And it touted various benefits of using the R3 metal liner as part of the R -- as part of the Acetabular System, including for patients who were more active.

Mr. Shuker was a more active patient, more elderly but he was very, very active. In fact, he has a -- a gym in his own home that he worked out at.

And Dr. Terefenko was very aware of Mr. Shuker's relative -- relatively -- impressive level of activity at his age.

THE COURT: Seventy, I guess, is a young age --

MR. ZAJAC: Well, it --

THE COURT: -- or --

MR. ZAJAC: -- sure. Seventy is the --

THE COURT: I'm glad to hear that.

MR. ZAJAC: -- new sixty.

(Laughter at 3:06 p.m.)

MR. ZAJAC: And did not -- did not -- give any information about how that particular articulation of the metal liner with the R3 femoral components, it was never part of what the FDA approved for that metal liner, never studied or evaluated and said, this is a great option for you and your --

and patients like Mr. Shuker. Okay.

Now, do we know what was in Dr. Terefenko's head? No, we don't. Someday, I hope I'll get to depose him and ask him.

So, Dr. -- so, Dr. Terefenko without knowing that this particular articulation has never been clinically studied or evaluated, goes ahead and agrees to do it.

And lo and behold, some months later, Mr. Shuker begins to develop a pain in his hip, that they think is, maybe, one thing or another thing.

But one of the last things that they suspected is -- is metal sensitivity.

They eventually draw out some fluid, they put it under a microscope and they say, you know what, this is actually metal sensitivity. You've got metal on metal in there, we're going to have to take the whole thing out.

And when Dr. Terefenko takes it out, he finds, lo and behold, a lot of metal debris right at that junction between the metal liner and the R3 femoral heads. Okay.

That is the gist of it, we know that it's being called, the R3 metal liner. We know that the -- the surgical technique brochure that goes out, doesn't say anything about, don't use the metal liner. It goes through and explains the entire surgical technique for the whole procedure.

We know that the inserts to those R3 femoral components don't say anything about, guess what, Doctors, don't

pair this with an R3 metal liner, don't do that.

There's no -- there's no FDA regulation of that, because those R3 femoral components are 510K cleared. So, the FDA has never PMA approved any of that.

So, basically, the gist of it is, they allowed doctors to think and encouraged them to think, this is a great option for them to use. The doctor uses it. We end up with -- with a metal-on-metal problem.

THE COURT: Okay.

MR. ZAJAC: I could drill down -- I mean, this goes on for page after page after page, where we say that things would have played out differently. I mean, I -- because four or five pages -- we do the best we can based on what we know at this point, your Honor.

THE COURT: Very well.

MR. ZAJAC: Based on what he know, we put it together as best we can and this -- this goes back to the Cullen case. I understand your Honor permitted discovery, but you've permitted discovery only on the issue of what the classification status was, not -- not what, they specifically represented to doctors.

I -- I couldn't take Dr. Terefenko's deposition and say, you tell me, Doctor, what did they -- what did they -- what did Smith & Nephew tell you about the use of the metal liner?

That's -- that's what discovery is for and I think, the Cullen case from the Western District recognizes that.

There are practical considerations here. I can't prove the entire case at this point.

THE COURT: Very well.

Let me try a similar question with regards to your parallel claim. Count 2, it appears to me of your first and the second amended complaint, it appears to me is the claim based on negligence based on violations of federal law and regulations.

And it seems to me, it is the count dealing with the parallel claim, am I correct, Count 2 --

MR. ZAJAC: The point of Count 2 is --

THE COURT: -- Count 2 --

MR. ZAJAC: -- to articulate parallel claims, should the Court find preemption.

THE COURT: Okay.

Now, it took you ten -- twenty -- pages in your second amended complaint to sort of lay it out.

And what I want you to do is -- as succinctly as you can -- and not by -- you know -- with -- with as many facts as you can that support your theory of parallel claim to tell me -- very succinctly -- not to throw regulations for me to read, the regu -- the Federal Safety standards.

But what Federal Safety standards, you believe, he -- he violated and you've listed them. But I think more importantly, how those violations, you believe, caused the injury -- the violation of those things caused the injury?

Because just giving me the code is -- it's not enough.

MR. ZAJAC: Okay.

Well, I don't know what else to tell you with this limited record, other than to tell you that Dr. Terefenko and/or my client would have known that this was an untested, un-vetted combination of parts articulating with each other.

They were already at that point, there was -- it was bubbling to the surface, that metal-on-metal articulations had a problem.

And that had Dr. Terefenko known, had my client known, they would have said, you know what, I don't want the metal liner. I don't want the added risk that's coming from using that metal liner with these particular femoral components rubbing up against each other, despite the representations and the indications from the -- from the manufacturer, that it seems to be perfectly okay to do it.

THE COURT: Very well.

MR. ZAJAC: I -- I can't -- again, I can't get into Dr. Terefenko's head and say what he knew, because I couldn't take his deposition.

THE COURT: All right.

When I take a look at the second amended complaint, you claim that they introduced the optional metal liner for the R3 Acetabular System, I believe, it was on February 27th of 2009, that's in your second amended complaint, Paragraph 91.

And the surgery was performed approximately, two months later on April 29th of 2009, that's according to your second amended complaint, Paragraph 106.

So, they argue that to the extent that you are claiming a parallel claim, based on the failure to report at-risk events to the FDA -- which you seem to be doing -- that the claims fail because you lack causation, because it is not plausible that enough adverse reports would have been generated in the two-month period between the option metal liner being introduced and the -- the preceding two months before Mr. Shuker's surgery to sort of, discourage your doctor from performing or using the R3 metal liner.

What is your response to that argument -- two months from the introduction -- that's the extension, right -- to have pre-market approval and your -- your doctor's use of the R3 metal liner?

MR. ZAJAC: Oh, I totally agree, two months would not have been enough.

But the re --

THE COURT: So --

MR. ZAJAC: -- the recall was not based on information that was gleaned from February of 2009 to April, 2009. The recall was based on information that was going back to Smith & Nephew in the UK and it was based on that information.

THE COURT: And what was that information?

MR. ZAJAC: That there was a much higher failure rate than what had originally been anticipated.

THE COURT: With what, failure rate with what?

MR. ZAJAC: With adverse events, including metal-on-metal sensitivity.

THE COURT: Okay.

MR. ZAJAC: So, the -- the genesis of the recall was not based on what was happening in the States. Here's an important fact and I apologize, I should have started with this.

The R3 metal liner was approved in Europe and other parts of the country for use with the R3 Acetabular System. So, it was being used in that fashion in Europe and other parts of the world.

And it was based on the feedback that was coming back into the UK that they said, we've got to pull this thing from the market.

So, I would agree that if the information was limited to the FDA in the States, I wouldn't have enough. But the record is showing that it was based on information globally coming back to Smith & Nephew in the UK.

THE COURT: Very well.

I think I understand, anything else?

MR. ZAJAC: No, your Honor, just to point out that this is a motion for summary judgment situation and all reasonable inferences are to be -- to be made in favor of the

non-moving party.

And that I would encourage the Court to consider my counter statement of material facts to be deemed admitted, because there was no effort under your rules to deny with particularity anything in my counter statement of material facts.

THE COURT: Okay.

MR. O'QUINN: And, your Honor, I -- I'd confess to you, I am not aware of an obligation to respond to the counter statement, I thought -- I was under the impression, we did not have to do that.

But we did include in our brief, basically, a paragraph that says, all of the counter statement is really irrelevant, anyway, because the only material fact here is that the R3 metal liner was PMA approved from the -- as part of the BHR system, so that's our position on that.

Your Honor, I've tried to make a list of the points and then, I'm going to try to do this as concisely as possible.

THE COURT: All right.

Maybe, I have some --

MR. O'QUINN: Sure.

THE COURT: -- some more -- following up on the packaging and the inserts in the --

MR. O'QUINN: Yes, sir.

THE COURT: -- in the R3 metal liner.

For doctor -- like, Dr. Terefenko here using it, off label in a hip replacement procedure, what package insert or labeling would he have received?

MR. O'QUINN: Well, first of all, your Honor, there's no allegation in the complaint, that he received this poly liner.

And doctor -- doctor -- excuse me -- Mr. Rouse's affidavit attached the correct surgical-technique brochure.

THE COURT: What is the difference between the poly and the --

MR. O'QUINN: Okay.

THE COURT: -- the other one.

MR. O'QUINN: Let's -- let's -- that's a good question.

The poly says, poly -- okay -- on the first page, it's the 510K approved poly liner that we talked about last time when we were here in March.

THE COURT: Okay.

MR. O'QUINN: Okay.

It's the poly liner. You'd go through this surgical-technique brochure, it does not demonstrate the technique with a metal liner. It makes no reference to the metal liner or any of the risks that would be associated with the metal liner.

It does not have any part numbers that would correspond to the metal liner. It's for the poly liner.

THE COURT: Now --

MR. O'QUINN: This is -- you know --

THE COURT: -- anybody who is trained, would know the difference between a poly and a metal liner, right?

MR. O'QUINN: I think it's -- thank you.

And not only that, the affidavit submitted by Mr. Rouse attached the labeling that Dr. Terefenko would have received. It is the Birmingham Hip Resurfacing brochure for the R3 Modular Acetabular Cups.

As I told you before, the cups -- and the liner -- got their own separate brochure and this document is almost thirty pages long, it's limited exclusively to the metal liner and several times it says, note that in the U.S. the R3 metal liner is intended for use as part of the BHR system only.

And by the way, he said that we weren't allowed to call it the R3 metal liner, this is the FDA's approval labeling, it calls it the R3 metal liner.

There is other inferences -- I won't go through them all but I've cited them. Here is another one, currently, Smith & Nephew does not have a commercially-available femoral head for use with a BHR resurfacing cup. Therefore, you have to use the resurfacing head, that's on Page 9.

So, the labeling that's the real labeling, not the poly labeling, clearly, discloses the regulatory status. It calls it an R3 metal liner and it discloses the risks associated

with its use and it was a separate brochure approved by the FDA.

There is not allegation that Dr. Terefenko saw this liner and as the Court pointed out -- come on -- he's an orthopedic surgeon. This guy is going to --

THE COURT: Right.

MR. O'QUINN: -- poly brochure and ignore the real label? I mean, that's just not plausible, your Honor.

THE COURT: Okay.

I'm going to look at it a little bit different --

MR. O'QUINN: Okay.

THE COURT: -- with regards to this labeling and this warning, because you have argued to me, that the FDA approved of the -- approval -- of the labeling and the warning for the metal liner, basically, says that you have to use that approval process in labeling and warning, because the state law cannot require any additional labeling or warning or modify the label and warning in any way, that's your argument if I understand it correctly?

MR. O'QUINN: Yes, sir.

THE COURT: I think predicated on the law.

But that's with regards to the metal liner and my question to you now is -- and I understand that both of these are in strict -- intrinsically, linked.

Can state law require additional warnings for the R3 Acetabular System which did not receive pre-market approval or

any kind of approval?

MR. O'QUINN: That's an excellent question. And the answer is, no, because you're coming --

THE COURT: Why not?

MR. O'QUINN: -- in the back door, you're telling -- you're telling Smith & Nephew, that we have to put warnings about how the metal liner should be used in other product labeling besides the metal liner labeling. That is an end run, but it has the same effect. You're imposing a requirement on this liner, that the FDA did not impose.

For example -- that's a great question -- let me see if I can think of an example. You know, the example, we'll put in the femoral head lining, that you shouldn't use it -- you shouldn't use the liner off label.

THE COURT: Well, or --

MR. O'QUINN: The FDA has never said --

THE COURT: -- or --

MR. O'QUINN: -- you couldn't do that.

THE COURT: -- or they could modify the warnings about the R3 Acetabular System to warn that the system should not be used with a metal liner, for example.

MR. O'QUINN: No, they can't do that, your Honor, because the FDA approved labeling says, you can use it with the -- with the shell and the femoral component.

So, maybe, I don't understand your question.

THE COURT: Well, I'm trying to get at what you -- we're focusing on the metal liner --

MR. O'QUINN: Yes, sir.

THE COURT: -- on the warnings and the metal liner and they cannot be added or subtracted -- they cannot add or modify them --

MR. O'QUINN: Correct.

THE COURT: -- in any way, shape or form, because that would be a violation of -- of -- you have to follow the FDA approval.

But looking at the other device, the R3 Acetabular System -- okay -- which did not receive market -- pre-market approval. Can under state law, better warnings be required, so that for example, don't use this system with the metal liner -- it's a problem?

MR. O'QUINN: The answer is, no, because you're still --

THE COURT: Why?

MR. O'QUINN: -- imposing a requirement on the metal liner that the FDA did not impose, whether you put in another component's labeling or in the R3 labeling, we would be required to go beyond what the FDA said, we had to go with this labeling.

Anything we would put in that label, is over and above what the FDA told us to do for the R3 metal liner.

THE COURT: All right.

Could you touch upon -- I tried to get a response to the argument that -- that they make -- about taking a look at the devise as a whole and not the component -- component parts -- in conducting my preemption analysis.

And I think I pointed out that the device is this case, the -- it's a -- well, they argued that the device in this case is a Class 2 5K clear system.

But my question was, isn't it true that the FDA has never approved the 5K or pre-market approval process for the particular devise that was used in the surgery, looking at it in the argument of -- of the whole versus the component parts.

And my question was, doesn't the combination that has not been approved distinguish the present situation from those cases in which the 5K clear components are later incorporated into a device that received pre-market approval?

Do you follow my question?

MR. O'QUINN: I think so, your Honor, from the briefing and I think --

THE COURT: What -- what is your response, 'cause I wasn't very --

MR. O'QUINN: Well, it wasn't very clear to me, either and I think it's a good question. But the plaintiffs seem to be saying one of two things.

Either they're saying that, because it was approved with the system, it didn't get approved as a component. And I

think they've retreated from that. It clearly got approved as a component.

So, the question becomes what happens when the doctor uses it outside that system in an off-label fashion?

And I think the law is crystal clear, that it doesn't change the preemptive effect that attached to that FDA approval. The FDA has never given us a 510K approval for this liner.

The only way we were allowed to ship it in interstate commerce is by making it a part of the BHR system and labeling it as part of that system, which we did and it was used off label, that doesn't change it.

If I may also, your Honor, while it's fresh in my mind, Mr. Zajac raise several times what he claims to be the most important point he wants you to remember, a policy argument that the FDA has never looked at the articulation between this liner and this femoral head. That is true in every off-label use.

He said, in Regal, you know, the Supreme Court made it clear that you get a PMA because it's been vetted and tested, et cetera. The product in Regal had not been tested or cleared for an off-label use. It never is. What an off-label use means is, that you've not given enough information to the FDA for them to have made the determination whether they should clear it or approve it.

So, that policy argument applies to every off-label

use. It applied in the Supreme Court case in Regal and it applies in every off-label case. The FDA does not approve off-label uses, that's why they're off label.

THE COURT: Yes.

MR. O'QUINN: Excuse me, I wanted to throw in.

THE COURT: Okay.

I -- I guess, the troubling part from the beginning with -- with this case and I guess, it's -- it's the troubling part for the plaintiff is the fact that you have a component part of a different system, in this case, the BHR that is approved as a system -- that component part -- and then, it's taken and it's being used with another system to conduct a surgery.

And the -- the -- what I'm trying to get my head around is the fact that, that because it had pre-market approval, it -- it preempts, even though it's a component part of the new system.

MR. O'QUINN: Our position is not that there was a new system formed when the R3 liner was used off label. They keep saying, that's our position, it's not.

Our position is that their claim attacks the R3 metal liner. And I think they finally admitted that, they dance around it, they dodge around it, but that's what all their papers say.

And --

THE COURT: I -- I think --

MR. O'QUINN: -- you can't change that, because it was used off label.

And I -- I'll say this, it is a very unique body of law, because you've got this very arcane regulatory system about how devices are put on the market and how they're controlled and -- and labeled, so -- and I can understand, obviously, it is kind of complicated.

But if you look at the case law, I think the -- the result is pretty clear, you can't change the design or labeling when it came to this component, even if it was used off label.

And they cannot show you and still have not shown you a plausible parallel claim.

When you asked about the -- the off-label promotion to Dr. Terefenko, they mentioned the press release, it's attached to my opposition, the second sentence:

> The metal liner was recently approved by the Food and Drug Administration for use with the Birmingham Hip Resurfacing system.

The second sentence discloses the regulatory status. The labeling discloses the regulatory status.

And he -- and Mr. Zajac keeps saying and I've had a limited record. Your Honor, he -- he's submitted sixty-nine requests for production to us. Forty-two requests for production to the FDA.

The original discovery cutoff in this case was in March, it wasn't until we filed the preemption motion and heard it in March, that your Honor pushed everything back. They never took Dr. Terefenko's deposition.

And furthermore, Dr. Terefenko is Mr. Shuker's doctor. Why can't he just pick up the phone and say, I'd like to make an appointment to see how this product was marketed to you?

But as we sit here today after all of this time and all of this opportunity, we've got a press release that discloses the regulatory status.

THE COURT: Very well.

(Pause at 3:28 p.m.)

THE COURT: Let me -- let me ask -- I think, Attorney Zajac took issue with my statement or -- or reading, 'cause I was trying to say whether -- is it a correct reading of the complaint, that Mr. Shuker's injuries were caused by the metal-on-metal articulation of the components used in the hip replacement, so that both the use of the metal liner and the use of the metal femoral head --

MR. O'QUINN: Your Honor --

THE COURT: -- and he said it was too narrow.

MR. O'QUINN: He said that originally and did kind of spar with your Honor with -- on that a little bit. Eventually, I think, he did admit that all their claims go from the articulation of the metal liner with the other components.

And we can both -- he and I can both sit here -- but I can give you the citations.

THE COURT: Okay.

MR. O'QUINN: Paragraph 43 to 59 of the first amended complaint, it talks about -- and I've read it to your Honor in my argument -- the interfacing of the liner with the ball -- the -- the femoral head.

Your Honor asked, why was the market -- why was the product pulled from the market? The MHRA -- that's the United Kingdom regulatory agency -- reported that the R3 metal liner had a higher revision rate. That's Paragraph 50. Not in the other thing -- the liner.

And in Paragraph 59, Dr. Terefenko determined that the pain that Mr. Shuker was experiencing was caused by metal sensitivity due to the -- excuse me -- due to the degeneration of the metal-on-metal articulation. And again, that's defined in Paragraph 43 as the rubbing of the liner.

Then, in their response to the undisputed facts in Paragraphs 33 and 35, they complain about the articulation of the liner with the other components.

In their opposition to the motion for summary judgment, itself, on Pages 6 and 7 and 12, they argue that the problem was caused because of the articulation of the liner with the shell and the femoral component. There are no specific allegations relating to any other components, they're all

conjoined with the metal liner.

You don't have to believe me, obviously, you can look at it for yourself and that's what I would refer the Court to.

THE COURT: Okay.

So, the problems for the -- they won't have similar problems -- the product was pulled in the United States?

MR. O'QUINN: Yes, sir.

THE COURT: Do you remember when I questioned her about the two-month period as being sufficient --

MR. O'QUINN: Yes.

THE COURT: -- enough for you to be aware of the problems? She said, well, look back --

MR. O'QUINN: Right.

THE COURT: -- 'cause you have the same problems in England -- in -- where you were marketing it before.

MR. O'QUINN: It was a good answer on its feet, but it's wrong and here's why.

The product received FDA approval and was released in the United States in February of '09. We had already given to the FDA, all of the information about what it had done worldwide.

When you get a PMA, you come in and you say, here's this and here's that and this product is already on the market, so they already had information on the liner and the BHR system. That two-month window, wasn't going to change what the FDA had

just told us was okay.

So, it's kind of like the -- the clock started running again, when we got that FDA approval. All of that information that was out there worldwide was part of the FDA's calculus and the FDA approved it in 2009. And then, two months later, Mr. Shuker got a surgery that, unfortunately, turned out -- you know -- apparently, bad for him and -- you know.

THE COURT: Very well.

MR. O'QUINN: But there couldn't -- nothing in the U.S. changed that approval.

THE COURT: Okay.

MR. O'QUINN: Is there anything else, your Honor?

THE COURT: No, thank you. I think you've answered my questions.

MR. O'QUINN: Thank you very much, your Honor, I appreciate --

THE COURT: Thank --

MR. O'QUINN: -- it.

And I also appreciate your letting us re-file it as a summary judgment after the 12(b)(6) issues. Thank you very much.

THE COURT: Very well. Thank you very much.

I'll take it under advisement. I'll issue an order in due course.

MR. ZAJAC: Thank you, your Honor.

THE COURT: Thank you. Have a good day.

MR. ASTRACHAN: Thank you.

ESR OPERATOR: All rise.

THE COURT: Thank you.

We have a criminal case coming up.

(Adjourned in this matter at 3:31 p.m.)

* * *

C E R T I F I C A T E

I do hereby certify that the foregoing is a correct transcript of the electronic-sound recording of the proceeding in the above-entitled matter.

_____ Date: July 20, 2014

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